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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,488	12/21/2000	Steven M. Bowman	22956-67	8271

21125 7590 02/12/2004

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BOSTON, MA 02210-2604

EXAMINER
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DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/747,488		BOWMAN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Liliana Di Nola-Baron		1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 18-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Receipt of Applicant's amendment, filed on September 12, 2003, is acknowledged.

#### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,599,323 in view of Sawhney (U.S. Patent 6,605,294). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and the instant application are drawn to a compatible tissue implant comprising a polymeric foam and a mesh-reinforcing component. Claim 1 in the instant application differs from claim 1 in the patent in the fact that it includes a biological component in association with the implant. Thus, the patent is deficient in the sense that it does not include an active agent in the implant of the invention.

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Sawhney teaches that implants may include one or more active agents, including antibiotics, proteins and growth factors (See col. 13, line 52 to col. 16, line 17).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant disclosed by the patent by including an active agent in the implant to achieve local treatment at the site of the implant. The expected result would have been a successful implant. Because of the teachings of Sawhney, that implants may include active agents to be locally delivered, one of ordinary skill in the art would have a reasonable expectation that the implant claimed in the instant application would be successful in providing local treatment. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

The two sets of claims are largely coextensive and thus raise an issue of obviousness-type double patenting.

3. Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7-12, 24, 26 and 27 of copending Application No. 10/022182. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is directed to a method of treatment comprising providing the implant claimed in the instant application. The composition in the method claimed in claim 1 of the copending application differs from the composition claimed in claim 1 of the instant application in the fact that the density of the mesh

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is not recited, however, one of ordinary skill in the art would have been able to determine the optimal density of the mesh by routine experimentation. The two sets of claims are largely coextensive and thus raise an issue of obviousness-type double patenting if one of the applications becomes a patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/320751. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to a biocompatible implant comprising a polymeric foam and a reinforcing component. The composition claimed in the copending application differs from the composition claimed in claim 1 of the instant application in the fact that the density of the mesh is not recited, however, one of ordinary skill in the art would have been able to determine the optimal density of the mesh by routine experimentation. The two sets of claims are largely coextensive and thus raise an issue of obviousness-type double patenting if one of the applications becomes a patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusions***



5. Claims 1-17 are rejected.
6. Claims 18-53 are withdrawn from consideration.
7. Applicant's arguments filed on August 16, 2003 have been fully considered and found persuasive, since the prior art fails to teach or suggest an implant, wherein the mesh is interlocked with the foam.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached at 571-272-0206. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 5, 2004

  
  
JAMES M. SPEAR  
PRIMARY EXAMINER  
AU 1615